K063106

curasan

Abbreviated 510 (k) Summary:

JUN 11 2007

REVOIS® Implant System

1. SUBMISSION INFORMATION

Name and Address of the Sponsor:	curasan AG Lindigstrasse 4 63801 Kleinostheim Germany
Contact person:	Dr. Wolf-Dietrich Hübner, MD Medical Director Tel.: +49 – 6027 – 4686-325 Fax: +49 – 6027 – 4686-433 E – Mail: wolf.huebner@curasan.de
Registered U. S. Agent:	Dr. Eric Wiechert, Ph.D. 109 Shore Drive Garner, NC 27529, USA Phone: 919 – 772-8518, fax: 919 – 772-1300 E – Mail: ewiecher@bellsouth.net

2. DEVICE IDENTIFICATION

Proprietary Name:	REVOIS® Implant System
Common Name:	Dental implant system, dental implant abutment
Classification Name:	Endosseous Dental Implant, root-form and Endosseous dental implant abutment
Classification:	Class II, Special Controls
Classification regulation Number:	21CFR 872.3640 21CFR 872.3630
Product Code: Subsequent Product Code:	DZA, Endosseous implant NHA, Endosseous implant abutment

3. PREDICATE DEVICES

XiVE® Dental Implant System: K013867, K021318
XiVE® Transgingival Dental Implant System: K024004, K032284
Tapered Screw-Vent® Implant: K013227
Advent® Implant System: K011245
Certain® PREVAIL™ Implants: K061629

4. INTENDED USE

The REVOIS® Implant System is an implant system recommended for:

Surgical placement in the edentulous or partially edentulous jaw bone (upper or lower jaw bone) to create support for prosthetic devices such as single artificial teeth, fixed or removable bridges or dentures.

The titanium implant can be applied either in a one-stage surgical procedure with immediate loading when good primary stability is achieved and with appropriate occlusal loading, or in a two-stage surgical procedure (after osseointegration of the implant).

Angled abutments on small diameter implants (3.8 mm) of the REVOIS® Implant System are intended for the anterior region of the mouth and not intended for the posterior region of the mouth due to limited strength of the implant.

5. DESCRIPTION OF THE DEVICE

The REVOIS® Implant System is a self-contained, modular dental implant system for placement into the jaw bone (upper or lower jaw bone) to support prosthetic devices for dental restoration. The system is designed for one-stage or two-stage surgical procedures.
The REVOIS® Implant System is composed of a titanium, screw type implant, pre-assembled with a multifunctional precision abutment and a transfer tool that snaps onto the abutment (Snap-on-tool). The implant is also available with a transfer tool only. A cover screw is contained in the top of the snap-on or transfer tool.
The system offers implants in various diameters and lengths (3.8; 4.3; 5.0 mm diameter; 9; 11; 13; 15 mm lengths). The REVOIS® Implant System is provided with a number of corresponding tools and surgical instruments, as well as a variety of prosthetic components. For ease of identification the implants and corresponding tools are color coded according to diameter.

The main components of the implant system are made of Grade IV or Grade V Titanium (implant, abutment) or plastic (snap-on tool, transfer tool). The materials comply with the ASTM standards ASTM F067 (implant), ASTM F0136-2a (abutment) and ASTM F2026 (Snap-on tool, Transfer tool). The implant surface is blasted with zirconium and then acid-etched for roughness.

The REVOIS® titanium implant (pre-assembled with the multifunctional precision abutment and snap-on-tool or with the transfer tool only) is supplied in double sterile packages (sterile inner plastic vial in a sterile glass vial, which is sealed in a blister) and is for single use only.
Tools and other re-usable instruments must be sterilized prior to use.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The REVOIS® Implant System is substantially equivalent to a variety of currently marketed and cleared dental implants or implant systems, such as the XiVE® or XiVE® TG Dental Implant System, the Tapered Screw-Vent® implants, the AdVent® Implant System, or the Certain® PREVAIL™ Implants.

All of those systems feature root form, screw type, endosseous implants made of titanium, and corresponding tools, instruments and accessories. Color coding of components is used in all systems compared for this submission to simplify identification and prevent mix-up of non-coordinating parts. The systems are essentially similar regarding intended use, indications, target population, anatomical sites, implant diameters and lengths, implant to abutment connection, materials used and performance aspects. In addition, all systems presented have a treated, roughened surface and tapered implant bodies.
A one-stage or two-stage surgical procedure is possible with the REVOIS system or any of the predicate devices.

Despite slight differences in device design (the REVOIS implant system features a unique multifunctional precision abutment combined with a snap-on/transfer tool), substances used for surface treatment, and titanium grades used for the implant itself, the information provided in this submission supports and confirms the substantial equivalence claim of the REVOIS® Implant System when compared to the predicate devices. The differences outlined in the SE comparison evaluation/discussion between the REVOIS® system and the predicate devices, do not affect the safety or effectiveness of the REVOIS® Implant System.

7. STATEMENT OF TECHNOLOGICAL COMPARISON

The REVOIS® Implant System provides state-of-the art implant technology and options that are comparable to the technology of the predicate devices. The design and pre-assembled version of implant, abutment (which fits for all implants and implant diameters) and snap-on/transfer tool offers easy handling for the dentist/surgeon by reducing the number of components needed for successful placement of the implant, while ensuring precision and stability. Multifunctional parts (e.g. precision abutment and transfer tool) save time and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2007

CURASAN AG
C/O Dr. Eric Weichert
President
Applications Specialists International, Incorporated
109 Shore Drive
Garner, North Carolina 27529

Re: K063106
Trade/Device Name: Revois Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: NHA
Dated: May 30, 2007
Received: May 31, 2007

Dear Dr. Weichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

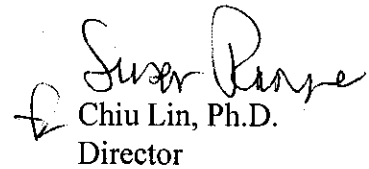
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K063106

Device Name: REVOIS® Implant System

Indications for Use:

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Surgical placement in the edentulous or partially edentulous jaw bone (upper or lower jaw bone) to create support for prosthetic devices such as single artificial teeth, fixed or removable bridges or dentures.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K063106